UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

BOBBY WISEHART,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	**Cause No.**
	)	
	)	
ZIMMER HOLDINGS, INC., ZIMMER INC, and ZIMMER US, INC.	)	**JURY TRIAL DEMANDED**
	)	
	)	
Defendants.	)	

COMPLAINT

NOW comes Plaintiff, Bobby Wisehart, by and through his undersigned counsel, hereby commences this individual action against Zimmer Holdings, Inc., Zimmer Inc., and Zimmer US, Inc. (hereinafter collectively "Defendants" unless otherwise stated) for compensatory and punitive relief. Plaintiff makes the following allegations based upon his personal knowledge as to his own acts, and upon information and belief, as well as upon his attorney's investigative efforts as to Defendants' actions and misconduct, and alleges as follows:

INTRODUCTION

1. This product liability action relates to the design, development, manufacture, testing, marketing, promotion, distribution, and sale of Zimmer's defective hip implant component known as the Durom Acetabular Component (the "Durom Cup").

2. The Durom Cup was surgically implanted in Plaintiff, Bobby Wisehart, on February 5, 2008. As a result of the Durom Cup's failure, Bobby Wisehart has had to change his life dramatically after suffering extensive pain following his implant. After the surgery, Mr. Wisehart continued to suffer pain in his buttock, hip area, groin and down his leg. Plaintiff still suffers incredible leg and hip pain. The pain has limited his ability to perform basic day-to-day functions.

3. Zimmer, founded in 1927, is one of the leading competitors in the U.S. hip and knee replacement market and accounted for seventy percent of the market in 2008.

4. In 2008, the U.S. hip and knee replacement market was valued at $6.7 billion dollars, with the hip replacement market contributing thirty-eight percent of the market at roughly $2.5 billion dollars. According to Zimmer's 2008 Annual 10-K Report, Zimmer was number one in global market share for reconstructive hip components. In the period ending December 2008, Zimmer reported $1,279.5 million in hip component sales. Zimmer's total 2008 sales exceeded $4 billion.

5. Zimmer designs, develops, manufactures, markets, tests, distributes and sells reconstructive orthopedic implants, including joint, dental and spinal implants, trauma products and related orthopedic surgical products. Zimmer's related orthopedic surgical products include surgical supplies and instruments designed to aid in orthopedic surgical procedures. Zimmer also has a limited array of sports medicine products. Zimmer's primary customers include musculoskeletal surgeons, neurosurgeons, oral surgeons, dentists, hospitals, distributors, healthcare dealers and, in their capacity as agents, healthcare purchasing organizations or buying groups. These customers range from large multi-national enterprises to independent surgeons.

6. Zimmer's Durom Cup is an orthopedic device used in total hip replacement surgeries. Hip replacement surgery, also known as hip arthroplasty, is a surgical procedure in which the patient's hip joint is resurfaced and replaced with an artificial implant. It is typically used to repair joint/bone damage or to treat arthritis pain in the hip joint area. The hip joint is in essence a large ball-and-socket joint composed of two parts: the head of the thighbone, or femur; and the acetabulum, a cup-shaped bone in the pelvis. Therefore, hip replacement surgery traditionally consists of two tasks: (1) replacing the end of the femur, or thighbone, with an artificial "ball," typically made of metal or stainless steel; and (2) resurfacing the hip socket

using a metal shell and plastic liner, into which the ball attached to the femur will fit.

7. During hip replacement surgery, damaged portions of the hip are replaced with smooth, durable artificial surfaces to allow the joint to function properly. The Durom Cup is not cemented or screwed in place during implantation. Instead, it was designed to bond to the patient's hip bone. The outside of the Durom Cup is porous, and has been sprayed with a highly engineered substance that is intended to facilitate the cup's acceptance by the human body. It is purportedly intended that the patient's own bone will grow into the exterior shell of the cup. This bone in-growth into the porous shell is what is intended to hold the cup in place.

8. Rather than functioning in the intended manner, the Durom Cup implant resists bone growth and as a result, instead of adhering to the bone, it comes loose and/or pops free from the hip, which can cause damage to the pelvic bone. This unintended result causes extreme and devastating pain and necessitates revision surgery to remove the failed Durom Cup and replace it with a product that functions properly.

9. The Durom Cup is part of a metal-on-metal hip implant system, which was widely sold as being more durable, especially in young and active patients, like Plaintiff Bobby Wisehart.

10. According to an article published in the ***New York Times***, on Thursday March 4, 2010, entitled, "Concern Over Metal-on-Metal Implants", "studies in recent years indicate that in some cases the devices can quickly begin to wear, generating high volumes of metallic debris that is absorbed into a patient's body. That situation can touch off inflammatory reactions that cause pain in the groin, death of tissue in the hip joint and loss of surrounding bone." In Bobby Wisehart's case, he, like the other patients in the studies, may have suffered from metal debris causing death to the soft tissue and bone surrounding his hip, and further decreasing his chances for a successful second hip replacement.

11. The suspension of the sales of Zimmer's Durom Cup, announced on July 22, 2008, affects thousands of patients. The Durom Cup has been implanted in over 12,000 patients in the United States since it was first sold on the U.S. market in 2006.

12. When introducing the Durom Cup, Zimmer represented that the Durom Cup would provide greater range of motion and less wear on the bearing than traditional hip replacement implant components, thus making it an ideal product for younger, active patients. Contrary to Zimmer's representations, the Durom Cup is prone to an unprecedented failure rate for hip replacement implant components.

13. Since Defendants first began selling the Durom Cup in the United States in 2006 through on or about July 22, 2008, the product labeling and product information for the Durom Cup failed to contain adequate information, instructions, and warnings concerning implantation of the product and the risks that the Durom Cup can loosen and separate from the acetabulum (hip socket) in patients.

14. Despite their knowledge of the serious injuries associated with use of the Durom Cup, Defendants engaged in a marketing and advertising program which, as a whole, by affirmative and material misrepresentations and omissions, falsely and deceptively sought to create the image and impression that the use of the Durom Cup was safe.

15. At all relevant times, Zimmer knew or should have known that the Durom Cup was not safe for the patients in whom it was implanted, including Plaintiff Bobby Wisehart, because of the unacceptable failure rate, which is approximately 24%, according to one leading hip surgeon.

16. Notwithstanding the knowledge of predicted failures with the defective Durom Cup, Zimmer continued to sell the Durom Cup for implantation in patients until July 22, 2008, when Zimmer announced a suspension of the sale and distribution of the Durom Cup.

Plaintiffs and patients in whom the Durom Cups remain implanted, not only have suffered physical injuries, they also bear an unacceptable increase in the risk of severe pain and disability, with or without a costly and painful revision surgery. The revision surgery is invasive and painful and is often needed to replace the defective Durom Cup implant.

JURISDICTION AND VENUE

1. As a direct and proximate result of the acts and omissions of the Defendant, Plaintiff has sustained permanent and devastating injuries. These injuries have caused, and will continue in the future to cause, extensive pain and suffering, emotional distress, loss in Plaintiff's ability to enjoy life; lost wages and future lost wages, and the expenditure, past and future, of substantial sums of money for medical, hospital, and related care, all to the Plaintiff's general damage in a sum in excess of seventy-five thousand dollars, ($75,000.00).

2. This Court has jurisdiction pursuant to 28 U.S.C. §1332 because the amount in controversy exceeds $75,000.00, and because there is complete diversity of citizenship between the Plaintiff and Defendant.

PARTIES

3. Plaintiff, Bobby Wisehart, is a citizen and resident of Cisco, Illinois.

4. At all times relevant to this Complaint, Plaintiff was a citizen and resident of Cisco, Illinois.

5. Defendant Zimmer Holdings, Inc. is a Delaware corporation organized, existing and conducting business in the State of Delaware with its principal place of business at 345 East Main Street, Warsaw, Indiana, 46580-2746. At all times relevant to this Complaint, Zimmer Holdings, Inc. was engaged in the business of manufacturing, marketing, testing, promoting, selling and/or distributing the Durom Cup, including to Plaintiff. At all times relevant herein, Zimmer Holdings, Inc. regularly transacted, solicited and conducted business in Illinois and

Missouri, including the marketing, promoting, testing, selling and/or distribution for the sale of the Durom Cup.

6. Zimmer, Inc. is a Delaware corporation. At all times relevant herein, Zimmer, Inc., was engaged in the business of manufacturing, marketing, testing, promoting, selling and/or distributing the Durom Cup. At all times relevant herein, Zimmer, Inc. regularly transacted, solicited and conducted business in Illinois and Missouri, including the marketing, promoting, selling and/or distribution for the sale of the Durom Cup.

7. Zimmer US, Inc. is a Delaware corporation. At all times relevant herein, Zimmer US, Inc., was engaged in the business of manufacturing, marketing, testing, promoting, selling, and/or distributing the Durom Cup. At all times relevant herein, Zimmer US, Inc. regularly transacted, solicited and conducted business in Illinois and Missouri, including the marketing, promoting, selling and/or distribution for the sale of the Durom Cup.

FACTUAL ALLEGATIONS

BACKGROUND ON ARTIFICAL HIPS AND HIP REPLACEMENT DEVICES

8. The human hip joint consists of two parts: a ball and a socket. A portion of the pelvic bone forms a cup-shaped socket; the ball at the top of the thigh bone fits into it. The ball is surrounded with cartilage which, in a healthy hip joint, allows the ball to move smoothly within the socket. Conditions such as osteoarthritis and avascular necrosis can cause degeneration of the hip joint such that hip replacement is required. A hip implant is designed to replicate the human anatomy — that is, the relatively simple ball and socket structure of the human hip joint. Total hip replacement surgery involves implanting an artificial ball and socket into the patient.

9. The artificial hip implantation process requires a surgeon to insert a metal cup with a smooth lining into the patient's diseased pelvic socket. The lining serves the same

purpose as natural cartilage: allowing for smooth movement of the ball portion of the thigh bone. The diseased or degenerated ball part of the thigh bone is then removed and replaced by a metal or sometimes ceramic ball mounted onto a thin metal stem. The metal stem is then fit into the thigh bone. Finally, the ball is placed securely into the pelvic socket that has been fitted with the artificial metal cup, where it should move easily, without friction or pain to the patient.

10. Total hip replacement is most commonly used to treat joint failure caused by osteoarthritis. Other indications include rheumatoid arthritis, avascular necrosis, traumatic arthritis, protrusion acetabuli, certain hip fractures, benign and malignant bone tumors, arthritis associated with Paget's disease of the bone, ankylosing spondylitis and juvenile rheumatoid arthritis. The aims of the procedure are pain relief and improvement in hip function. Hip replacement is usually considered only once other therapies, such as pain medications, have failed.

11. Total hip arthroplasty (“THA”) , or total hip replacement, is a common medical procedure performed on more than 420,000 patients in the U.S. each year. It is designed to help relieve pain and improve joint function in people with severe hip degeneration due to arthritis or trauma. Traditional devices to replace degenerative hips utilize implantable metal or ceramic heads fitting into a modular metal-backed polyethylene bearing. One concern that historically plagues successful THAs is the wear of the bearing. As the THA becomes more common among younger patients who want to maintain a physically active lifestyle, alternative bearing surfaces such as cross-linked polyethylene, ceramic-on-ceramic and metal-on-metal have been developed to address the issue of wear. The Durom Cup promised to offer an alternative surface that would resist wear and tear.

12. The Durom Cup is a monoblock (constructed of a single piece of material) cup made of cobalt chromium (CoCr) alloy and is designed for use in combination with Zimmer’s

Metasul Metal-on-Metal Tribological Solution LDH (Large Diameter Heads) for THA. The design and material of the Durom Cup are key elements to its intended stability, wear resistance, and bone sparing characteristics. The Durom Cup has a pure titanium plasma-sprayed coating for fixation. The coating on the Durom Cup sold in the United States has a different structure and is slightly thicker (0.1mm) compared to the same products which were sold for use in patients outside of the United States.

II. HISTORY OF THE DUROM CUP

13. The Durom Cup was launched in Europe in 2003 for hip resurfacing. Hip resurfacing requires less bone removal than conventional THA, but necessitates a different surgical technique. The Durom Cup was made available in Canada and Australia in 2003, India and Korea in 2005, and Argentina in 2006.

14. On or about December 19, 2005, Zimmer submitted a section 510(k) Premarket Notification of Intent (K053536) to the FDA to manufacture and market the Durom Acetabular Component and the Metasul LDH (Large Diameter Heads) devices to the public. Three months later, on March 19, 2006, the FDA cleared the device for marketing and distribution in the United States.

15. The 510(k) approval process by the FDA is regarded as a simplified “me too” application process, which does not require extensive review and approval by the FDA. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device that is not subject to premarket approval. Submitters simply must compare their device to one or more legally marketed devices (devices marketed prior to May 28, 1976) and make and support their substantial equivalency claims. The FDA does not perform 510(k) pre-clearance facility inspections and submitters may market the device immediately after 510(k) clearance is granted.

16. In this instance, Zimmer submitted a simplified 510(k) application that compared the Durom Cup to earlier products called "predicate devices" manufactured by competitors. In its application, Zimmer described: "The proposed device has the same intended use, has similar performance characteristics, is manufactured from similar materials using similar processes, and is similar in design to the predicate devices."

17. No clinical studies were conducted in connection with the submission of the application for the Durom Cup. As part of the application process, Defendants stated that the "results of non-clinical analysis demonstrate that the device is safe and effective and substantially equivalent to the predicate device (as implants)." Further in their submission to the FDA the Defendants repeat throughout that the Durom Cup is intended to be a device that is simply similar to previously approved predicate devices. Therefore, the FDA was persuaded by Defendants that any additional review and investigation was unnecessary.

III. DESIGN & MANUFACTURE OF THE DUROM CUP

18. Zimmer's Durom Cup is a flattened hemisphere, which is meant to offer a greater range and freedom of movement. With a constant wall thickness of 4 mm throughout all sizes, the cup maintains an inner diameter as large as possible, while intended to maintain maximum implant strength and minimum bone resection of acetabular bone mass. A coating of pure titanium using a plasma spray under vacuum and static load is applied to the outer surface, called Porolock (tm) Ti VPS. The high carbon cobalt chromium (CoCr) alloy is produced by a forging rather than casting process. This means that the size of block carbides is up to eight-times smaller compared to cast cobalt chromium (CoCr) prostheses. The resulting lower surface roughness was intended to lead to a lower wear rate when compared with cast cobalt chromium (CoCr) alloys.

19. Zimmer failed to recognize the deficiencies of the Durom Cup due to poor and

inadequate quality assurance procedures, including failure of Zimmer to implement appropriate physical, manual, x-ray, microscopic and other inspections of the Durom Cup. Zimmer failed to implement or utilize adequate safeguards, tests, inspections, monitoring and quality assessments to ensure safety of the defective device. At the time the devices were manufactured and sold to patients, the devices were defectively manufactured and unreasonably dangerous, and did not conform to the federal regulations subjecting patients to risks of injury.

20. During the time Zimmer manufactured the Durom Cup, inadequate manufacturing processes led to material flaws in the quality systems at its manufacturing facilities.

21. During the course of manufacturing the Durom Cup, Zimmer failed in several ways, including, without limitation, by:

(a) failing to conduct adequate mechanical testing on components, subassemblies and/or finished Durom Cup;

(b) failing to test an adequate number of sample devices on an ongoing basis;

(c) failing to take adequate steps to specifically identify failure modes with clarity and suggest methods to monitor, avoid, and/or prevent further failures;

(d) failing to identify and/or note the significance of any testing that resulted in failure of the Durom Cup;

(e) failing to take corrective actions to eliminate or minimize further failures of the Durom Cup;

(f) failing to adequately explain performance specifications for the components, subassemblies, and finished Durom Cup;

(g) failing to adequately explain or justify all test conditions and acceptance criteria for the Durom Cup;

(h) failing to perform adequate testing in an environment that adequately simulated in vivo conditions; and, by

(i) failing to perform adequate quality assurance testing before and after sterilization.

22. Zimmer failed to perform adequate testing of the Durom Cup, including its components and subassemblies, to ensure that the Durom Cup functioned properly during and after implantation.

23. As a result of these manufacturing and quality control problems associated with the manufacture of the Durom Cup, the component was inadequately and defectively manufactured making it adulterated, and outside of the specifications expressly approved by the FDA.

IV. DUROM CUP DEFECTS ARE EXPOSED BY LEADING PHYSICIANS

24. After the FDA initially approved of the 510(k) application, Zimmer began to aggressively market the Durom Cup to physicians.

25. Relying upon Zimmer's representations, physicians began using broadly the Durom Cup instead of other models. Reports of Durom Cup failures soon followed. It is now apparent that a significant percentage of the Durom Cups have failed, and that the failure rate is unacceptably high.

26. The failure rate is estimated at upwards of 24% (twenty-four percent) when analyzing patients over a four-year period (2006-2010). This failure rate is much higher than similar products made by Zimmer, and is also much higher than the failure rate of competitor's devices. Furthermore, this rate is four times Zimmer's predicted failure rate of 5.7%

27. Lawrence Dorr, M.D., a world-renowned orthopedic surgeon and Zimmer

consultant, and a team of doctors at The Arthritis Institute at Good Samaritan Hospital in Los Angeles, California, have recently published the results of their study comparing one hundred and eighty patients who had the large-diameter (44- to 50-mm) Durom Cup and fifty-four patients who had a small-diameter (28-mm Metasul®) articulation implanted between May 2006 and November 2007. The total number of clinical failures was forty-one of one hundred and eighty patients (23%). Twenty-eight of one hundred and fifty-one patients had radiographic impending failure at final follow-up (18.5%). All post-revision surgery retrieved cups were examined in detail and had no evidence of bone on the fixation surface.

28. Since at least 2007, surgeons implanting the Durom Cup complained to Zimmer that the device was failing in their patients, many of whom had to undergo painful, invasive and expensive revision surgeries.

29. One of these surgeons was Dr. Dorr, who warned Zimmer in 2007 of the high rate of Durom Cup failures. At the time Dr. Dorr warned Zimmer of the high rate of failures, he was a veteran of thousands of hip replacement surgeries.

30. In particular, Dr. Dorr informed Zimmer that x-rays showed that the Durom Cup was failing because it was separating or loosening from the bone, rather than fusing to it, causing patients crippling pain while the metal cup moved around the hip socket and rubbed against the bone.

31. Zimmer ignored Dr. Dorr's warnings and continued to sell the Durom Cup.

32. In April 2008, Dr. Dorr publicly warned other orthopedists about the cup failures his patients were experiencing and urged Zimmer to stop selling the Durom Cup.

33. On April 22, 2008, Dr. Dorr wrote the following memorandum to his colleagues at the American Association of Hip and Knee Surgeons:

MEMO
DATE: 4/22/08
TO: American Association of Hip and Knee Surgeons
FROM: Larry Dorr, M.D.
RE: This NOTICE is to inform you that we have had ten revisions in 165 hips and have four more that need to be revised using the Durom cup (Zimmer, Inc).

This failure rate has occurred within the first two years. In the first year the x-rays looked perfect. We have revised four that did not have any radiolucent lines or migration (and John Moreland revised one). These early cups fooled us, but the symptoms were so classic for a loose implant that we operated the patients. When we hit on the edge of the cup it would just pop free. As time goes by the cups begin developing radiolucent lines. We now have one cup at two years that has actually migrated a short distance. It has tilted into varus. We do not believe the fixation surface is good on these cups. Also there is a circular cutting surface on the periphery of the cup that we believe prevents the cup from fully seating. We stopped using the cup after the first revisions.

We have notified Zimmer. The FDA has been notified and we will notify them of our continued revisions. The company does not believe it should pull the cup from the market so I am notifying all of my colleagues of our failure rate with this cup. I went through a similar scenario with the Sulzer cup failures where I was the only one experiencing revisions at the beginning and basically it was assumed that it was our technique. I can assure you that this goes beyond technique. I learned my lesson in not informing everyone about this magnitude of failures with the Sulzer cup problem, so it is my obligation to do so with this cup.

(emphasis in original).

34. After informing colleagues about his experience with the Durom Cup, Dr. Dorr heard from several other doctors who reported similar problems. According to Dr. Dorr and other physicians, x-rays of patients who received defective Durom Cups showed that the socket was separating from bone, rather than fusing with it.

35. For patients (including Plaintiff), the slippage of the implant itself, as a result of its failure to adhere to the bone meant agony as the metal cup moved around in the hip socket and rubbed against bone. Such crippling injuries are devastating to patients as they were to Mr. Wisehart.

36. Despite this memorandum, Zimmer 5 ignored the warnings and continued to sell the Durom Cup.

37. In late May 2008, Zimmer finally informed surgeons that it was investigating Dr.

Dorr's complaint; but, it did not suspend sales, as Dr. Dorr had recommended. While Zimmer investigated complaints, roughly 1300 more patients were implanted with the Durom Cup in the United States.

38. Zimmer responded by defending the Durom Cup and blaming the doctors' implantation techniques. Zimmer later attributed failures of the Durom Cup to a discrepancy in doctors' techniques in performing THA surgeries. Zimmer contended (and still contends) that the technology and design parameters of the Durom Cup demand a surgical technique with "high precision and specificity compared to more common and familiar hip arthroplasty surgical techniques practiced in the U.S." Therefore, according to Zimmer, the Durom Cup requires additional training in implantation technique and cup placement for many surgeons who use the device and who may otherwise may be experts in THA.

39. Around this time, although Zimmer still maintained that there were no issues with Durom Cup, other doctors began to stop implanting them. Even still, Zimmer continued to market the Durom Cup to unsuspecting physicians and patients, selling hundreds of units between May 2008 and July 22, 2008.

40. Throughout 2008, while the Durom Cup was being implanted in patients across the United States and around the world, Zimmer was accumulating mounting and overwhelming reports that the Durom Cups were failing at an alarming and undisclosed rate.

II. TEMPORARY SUSPENSION OF THE DUROM CUP

41. Zimmer continued to sell the Durom Cups for implantation in patients until July 22, 2008, when Zimmer announced it was temporarily suspending the Durom Cups from marketing and distribution in the United States. In its announcement, Zimmer stated that the suspension was necessary "while the Company updated labeling to provide more detailed surgical technique instructions to surgeons and implements its surgical training program in the

U.S."

42. Zimmer announced that the company was taking this "voluntary action to address its concerns regarding reports of cup loosening and revisions of the acetabular component used in total hip replacement procedures" but that Zimmer "has found no evidence of a defect in the materials, manufacture, or design of the implant."

III. ZIMMER'S IMPROPER FAILURE TO RECALL DUROM CUP

43. Under federal regulations, a recall is "a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure." A recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the FDA.

44. These sections also recognize that recall is an alternative to an FDA-initiated court action for removing or correcting violative, distributed products by setting forth specific recall procedures for the Food and Drug Administration to monitor recalls and assess the adequacy of a firm's efforts in recall. A company's voluntary recall of a medical device and the FDA's classification of that action as a Class I recall establish that the device violates FDA regulations.

45. To date, Zimmer has not issued a public recall of the Durom Cup and instead has described its action as only a "temporary suspension" of the device. In reality, Zimmer has made the device "unavailable for purchase in the United States," (see screen shot from Zimmer e-catalog as published on Zimmer's website on February 23, 2010, but has not voluntarily recalled the device.

COUNT I – NEGLIGENCE

46. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

47. Defendants had a duty to exercise reasonable care in manufacturing, marketing, researching, testing, design, marketing, promotion, packaging, sale and distribution of the Durom Cup for public consumption.

48. Defendants failed to exercise reasonable care and were negligent through the following acts and omissions:

a. Manufacturing, designing, promoting, formulating, creating, marketing, packaging, distributing and selling the Durom Cup in violation of FDA approved requirements because the product was released for public use with a manufacturing and design defect(s) and improper functioning beyond that approved by the FDA;

b. Manufacturing, designing, producing, promoting, formulating, creating, marketing, distributing and selling the Durom Cup without properly testing it to ensure it did not have defect(s);

c. Manufacturing, designing, producing, promoting, formulating, creating, marketing, distributing and selling the Durom Cup in a manner that was dangerous to intended users because it had manufacturing and design defect(s) and improper functioning;

d. Failing to adequately warn, timely recall or otherwise notify health care providers and users at the earliest date that it became known that the Durom Cup was dangerous and defective;

e. Negligently advertising and recommending the use of the Durom Cup without ensuring the safety of the product for its intended use;

f. Failing to reliably establish the identity, strength, quality and purity of the the Durom Cup that Defendants released into the market; and

g. Failing to conduct adequate post-marketing surveillance to ensure the safety of the Durom Cup.

49. Defendants under-reported, underestimated and/or downplayed the serious dangers and the defective nature of the Durom Cup.

50. Defendants knew or should have known that consumers such as Plaintiff would foreseeably suffer serious injury as a result of Defendants' failure to exercise ordinary care as outlined above.

51. Defendants' negligence was a proximate cause of Plaintiff's bodily injuries and damages.

52. The defendants were negligent in manufacturing the Durom Cup because:

a. Their manufacturing process for the product did not satisfy the Food and Drug Administration's manufacturing standards;

b. The failure of the manufacturing processes for the product to satisfy the Food and Drug Administration's manufacturing standards for the devices resulted in unreasonably dangerous manufacturing defects, and;

c. The defendants failed to warn of the unreasonable, risks created by these manufacturing defects.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT II - STRICT PRODUCTS LIABILITY/ DEFECTIVE DESIGN

53. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

54. Defendants designed, produced, manufactured and injected into the stream of commerce, in the regular course of its business, the Durom Cup which it knew would be used by the Plaintiff and others.

55. At the time the Durom Cup was manufactured and sold to the Plaintiff by Defendants, it was defective in design and unreasonably dangerous, subjecting users to risks of long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health

consequences, and other illnesses which exceeded the benefits of the products, and for which other safer products were available. This defective condition made the product unreasonably dangerous when put to the reasonably anticipated use for which the Durom Cup was advertised.

56. Alternatively, when the Durom Cup products were manufactured and sold to the Plaintiff by Defendants, the products were defective in design, making the use of the product more dangerous than other similar products.

57. Plaintiff used the Durom Cup in a manner reasonably anticipated.

58. The Durom Cup sold to the Plaintiff reached the Plaintiff without substantial change. Plaintiff was unaware of the dangerous propensities of the product until well after his use and subsequent serious side effects including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health consequences. The Plaintiff used the the Durom Cup without making any changes or alterations to the product.

59. As a direct and proximate result of the defective and dangerous design of the the Durom Cup, Plaintiff has been damaged.

60. Defendants' conduct was done with conscious disregard for the safety of users of the Durom Cup, including the Plaintiff.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT III – STRICT PRODUCT LIABILITY/FAILURE TO WARN

61. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

62. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed the Durom Cup which was used by Plaintiff.

63. The Durom Cup was expected to, and did, reach the usual consumers, handlers and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, tested, sold, distributed and marketed by Defendants.

64. At all times relevant to this Complaint, the Durom Cup was in an unsafe, defective, and inherently dangerous condition which was unreasonably dangerous to its users, specifically including Plaintiff.

65. The Durom Cup was so defective in design, manufacture and testing that when it left the hands of Defendants, the foreseeable risks exceeded the benefits associated with the design and manufacture of the Durom Cup.

66. Defendants knew, or should have known, at all times relevant herein that the Durom Cup was in a defective condition and was inherently dangerous and unsafe.

67. Plaintiff used The Durom Cup for the purpose and manner normally intended for the product.

68. Plaintiff acting as a reasonably prudent person could not have discovered that the Durom Cup was defective, nor could he have perceived its danger.

69. Defendants had a duty to create a product that was safe for its normal, intended use.

70. Upon information and belief, sales and use continued after Defendants knew, or should have known that their product had a manufacturing and design defect(s) and was functioning improperly, and therefore, presented risk of serious side effects including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health

consequences. Therefore, Defendants are strictly liable in tort for the bodily injuries and damages suffered by Plaintiff.

71. The Durom Cup designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants had a manufacturing and design defect(s) and was functioning improperly, and was therefore, unreasonably dangerous, not reasonably safe, and did not meet reasonable consumer expectations because of design and manufacturing defects, use defects including inadequate warnings, and defects attributable to inadequate testing. Defendants are, therefore, strictly liable for the injuries and damages suffered by Plaintiff.

72. The Durom Cup designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants had a manufacturing and design defect(s) and was functioning improperly, and therefore, was defective due to inadequate post-marketing surveillance and/or warnings. Defendants are, therefore, strictly liable for the injuries and damages suffered by Plaintiff.

73. The Durom Cup designed, researched, manufactured, tested, advertised, promoted, marketed, sold and/or distributed by Defendants was unreasonably dangerous, because:

a. The manufacturing processes for the product did not satisfy the Food and Drug Administration's manufacturing standards;

b. The failure of the defendants' manufacturing process for the product to satisfy the Food and Drug Administration's applicable manufacturing standards resulted in unreasonably dangerous manufacturing defects, and;

c. The defendants failed to warn of the unreasonable risks created by these manufacturing defects.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT IV - STRICT PRODUCTS LIABILITY/ DEFECTIVE MANUFACTURING

74. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

75. Defendants designed, produced, manufactured and injected into the stream of commerce, in the regular course of its business, the Durom Cup which it knew would be used by the Plaintiff and others.

76. At the time the Durom Cup was manufactured and sold to the Plaintiff by Defendants, it was defectively manufactured and unreasonably dangerous, it did not conform to the federal regulations subjecting users to risks of serious side effects including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health consequences which exceeded the benefits of the products, and for which other safer products were available.

77. That Plaintiff's injuries resulted from the defective condition of Defendant's Durom Cup, the defective condition made the Durom Cup unreasonably dangerous, and the defective condition existed at the time the Durom Cup left the Defendants' control.

78. That the Defendants could reasonably be expected to foresee, and be responsible for, injuries to persons who were injured as a result of the manufacturing defect in the Durom Cup.

79. That Plaintiff is an individual to whom injury resulting from defectively manufactured Durom Cup is reasonably foreseeable and Plaintiff was using said Durom Cup for its intended purpose.

80. The Durom Cup sold to the Plaintiff reached the Plaintiff without substantial change. Plaintiff was unaware of the dangerous propensities of the product until well after Plaintiff's use and subsequent injuries. The Plaintiff used the Durom Cup without making any changes or alterations.

81. As a direct and proximate result of the defective and dangerous manufacturing of the Durom Cup, Plaintiff has been damaged.

82. Defendants' conduct was done with conscious disregard for the safety of users of the Durom Cup, including Plaintiff.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT V - NEGLIGENT DESIGN

83. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

84. Defendants designed, produced, manufactured and injected into the stream of commerce, in the regular course of its business, the Durom Cup which it knew would be used by Plaintiffs and others.

85. At the time the Durom Cup was manufactured and sold to Plaintiff by Defendants, it was defective in design and unreasonably dangerous, subjecting users to risks of serious side effects including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe

and permanent health consequences which exceeded the benefits of the product, and for which other safer products were available.

86. Alternatively, when the Durom Cup product was manufactured and sold to the Plaintiff by Defendants, the product was defective in design and making use of the product more dangerous than other similar products.

87. The Durom Cup sold to the Plaintiff reached the Plaintiff without substantial change. Plaintiff was unaware of the dangerous propensities of the product until well after his use and subsequent serious side effects including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health consequences. Plaintiff used the Durom Cup without making any changes or alterations.

88. In designing and manufacturing the Durom Cup, Defendants failed to exercise the ordinary care that a careful and prudent manufacturer would exercise in the same or similar circumstances.

89. As a direct and proximate result of the negligent design of the Durom Cup, Plaintiff has been damaged.

90. Defendants' conduct was done with conscious disregard for the safety of users of the Durom Cup, including Plaintiff.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT VI - NEGLIGENT FAILURE TO WARN

91. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

92. Defendants owed the Plaintiff a duty to warn of any dangerous defects or side effects; a duty to assure its product did not cause users unreasonable and dangerous risks, reactions, side effects; and a duty to provide adequate post market surveillance and warnings as it learned of the Durom Cup's substantial dangers.

93. Defendants breached its duty of reasonable care to the Plaintiff in that Defendants failed to:

a. Conduct sufficient testing which, if properly performed, would have shown that the Durom Cup sold to Plaintiff had serious side effects, including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health consequences, and warn users of those risks; and/or

b. Include adequate warnings with the Durom Cup products sold to Plaintiff that would alert users to the potential risks and serious side effects including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health consequences; and/or

c. Warn the Plaintiff that use of the Durom Cup sold to him carried a risk of permanent disability from including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health consequences; and/or

d. Advise the FDA, the health care industry, and the public about the adverse reports it had received regarding the Durom Cup sold to the Plaintiff; and/or

e. Provide Plaintiff with other appropriate warnings.

94. Defendants should have known that the Durom Cup caused unreasonably dangerous risks and serious side effects of which the general public would not be aware. Defendants nevertheless advertised, marketed and promoted its product knowing there were safer methods and similar products.

95. As a direct and proximate result of Defendants' negligence and breaches of its duty of reasonable care, Plaintiff has been damaged.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT VII - NEGLIGENT MANUFACTURING

96. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

97. Defendants designed, produced, manufactured and injected into the stream of commerce, in the regular course of its business, the Durom Cup which it knew would be used by the Plaintiff and others.

98. At the time the Durom Cup was manufactured and sold to the Plaintiff by Defendants, it was defective in design and unreasonably dangerous, subjecting users to risks of serious side effects, including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health consequences, and for which other safer products were available.

99. Alternatively, when the Durom Cup product was manufactured and sold to the Plaintiff by Defendants, the product was defective in design and manufacturing, making use of the product more dangerous.

100. The Durom Cup sold to the Plaintiff reached the Plaintiff without substantial change. Plaintiff was unaware of the dangerous propensities of the product until well after Plaintiff's use and subsequent injuries. Plaintiff used the Durom Cup without making any changes or alterations.

101. Defendants had a duty to exercise reasonable care and/or to comply with federal requirements regarding the design, manufacture, sale and/or distribution of the Durom Cup into the stream of commerce, including a duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events.

102. In designing and testing the Durom Cup, Defendants failed to exercise the ordinary care that a careful and prudent manufacturer would exercise in the same or similar circumstances.

103. As a direct and proximate result of the negligent manufacturing of the the Durom Cup, Plaintiff has been damaged.

104. Defendants' conduct was done with conscious disregard for the safety of users of the Durom Cup, including Plaintiff.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT VIII - NEGLIGENT MISREPRESENTATION

105. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

106. At all relevant times, Defendants knew, or should have known, that there were dangerous side effects resulting from the use of the Durom Cup.

107. Defendants knew or reasonably should have known that consumers such as the Plaintiff would not have known about the increased risk of serious side effects, including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health consequences associated with the use of the Durom Cup.

108. Defendants armed with the knowledge stated in the preceding two paragraphs, preceded with the design, production, manufacture, promotion, advertising, and sale of the Durom Cup without adequate warning of the side effects and dangerous risks to the consuming public including the Plaintiff.

109. Defendants negligently represented to the Plaintiff the safety and effectiveness of the Durom Cup and concealed material information, including adverse information regarding the safety and effectiveness of the Durom Cup. The misrepresentations and/or material omissions made by or perpetuated by Defendant are as follows, Defendants failed to:

a. Conduct sufficient testing which, if properly performed, would have shown that the Durom Cup sold to Plaintiff had serious side effects, including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health consequences, and warn users of those risks; and/or

b. Include adequate warnings with the the Durom Cup products sold to Plaintiff that would alert users to the potential risks and serious side effects including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health consequences; and/or

c. Warn the Plaintiff that use of the Durom Cup sold to him carried a risk of permanent disability from including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health consequences; and/or

d. Advise the FDA, the health care industry, and the public about the adverse reports it had received regarding the Durom Cup sold to the Plaintiff; and/or

e. Provide Plaintiff with other appropriate warnings.

110. Defendants made the misrepresentations and omissions with the intent for the Plaintiff and the consuming public to rely upon such misinformation or the absence of such misinformation in selection of the Durom Cup for their hip implant.

111. Plaintiff justifiably relied on and/or was induced by the misrepresentations and/or active concealment by Defendants and relied upon the absence of safety information which Defendants suppressed, concealed, or failed to disclose all to Plaintiff's detriment.

112. As a direct and proximate result of the dangerous and defective condition of the Durom Cup Plaintiff suffered serious side effects, including, but not limited to, long-term complications and pain and additional surgeries, personal injuries, the need for corrective surgery and pain and suffering, as well as other severe and permanent health consequences, and incurred economic damages in the form of medical expenses.

113. Plaintiff is entitled to recover from Defendant for all damages caused by the defective product including, but not limited to, damages for pain, suffering, mental anguish, emotional distress, loss of the capacity to enjoy life, lost past and future income and occurred expense.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT IX - INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

114. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

115. The acts, omissions, and representations of the Defendants regarding the manufacturing, distribution and marketing of the Durom Cup as described in the foregoing paragraphs were intentional, reckless, extreme and outrageous. Defendants intentionally engaged in extreme and outrageous conduct when they intentionally and/or recklessly marketed the Durom Cup and then intentionally and/or recklessly concealed material information about the Durom Cup potential serious adverse effects from Plaintiff and his physician(s), hospital(s), and

medical provider(s).

116. Defendants knew that Plaintiff would suffer mental distress and anxiety upon learning that the Durom Cup possessed a likelihood of serious adverse effects as described herein.

117. As a result of Defendants' misconduct, Plaintiff sustained and will continue to sustain emotional and mental distress and anxiety.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT X - NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

118. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

119. Defendants negligently and carelessly manufactured, sold and distributed to Plaintiff the Durom Cup, which was defective.

120. Defendants negligently and carelessly concealed the defective nature of the Durom Cup from Plaintiff, his physician(s), hospital(s), and medical provider(s).

121. Defendants negligently and carelessly misrepresented the usefulness, quality and safety of the Durom Cup to Plaintiff, his physician(s), hospital(s), and medical provider(s).

122. The Defendants' negligence and carelessness directly impacted the Plaintiff in that he was induced to purchase and use the defective and dangerous Durom Cup.

123. As a direct result of Defendants' misconduct alleged herein, Plaintiff has suffered and will continue to suffer emotional and mental distress and anxiety from the fear of knowing there is a likelihood of serious complications, which was caused by Defendants' product, the Durom Cup.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT XI -COMMON LAW FRAUD

124. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

125. Defendants either knew or should have known that the the Durom Cup sold to Plaintiff was dangerous and not as effective for its purpose as represented, and posed greater risks than disclosed, and otherwise not as represented to be as alleged above.

126. Defendants were under a duty to disclose this information to the Plaintiff under the common law as well as laws requiring it not to engage in false and deceptive trade practices, and as otherwise alleged in this complaint, because Defendants made representations and partial disclosures concerning the nature and quality of this product which they had a duty to correct, because Defendants were in a superior position to know the true state of the facts about the dangerous and defective nature of the Durom Cup sold to Plaintiff and its known risks to the Plaintiff. These deliberate and/or intentional omissions of material facts and misrepresentations include but are not limited to:

a. Suppressing, failing to disclose and mischaracterizing the known risks of using the Durom Cup sold to Plaintiff;

b. Failure to timely and fully disclose the actual results of clinical tests and studies related to the Durom Cup sold to Plaintiff;

c. Failing to issue adequate warnings concerning the risks and dangers of using the Durom Cup sold to Plaintiff, which would disclose the nature and extent of the side effects of the Durom Cup sold to Plaintiff;

d. Failing to disclose that adequate and/or standard and/or generally accepted standards for pre-clinical and clinical testing had not been done;

e. Failing to disclose that adequate and/or standard and/or generally accepted standards for post-marketing testing had not been done; and;

f. Making the representations concerning the safety, efficacy and benefits of the Durom Cup sold to Plaintiff as detailed in this complaint without full and adequate disclosure of the underlying facts which rendered such statements false and misleading.

127. Plaintiff did not know, and could not learn, the material facts and important information Defendants omitted and suppressed. The facts and information suppressed and concealed by Defendants are material, and of such a nature that it can be reasonably presumed that the suppression and concealment of such facts caused, contributed to, and/or was a substantial factor in causing the Plaintiff to use the Durom Cup and be exposed to such unnecessary risks.

128. As a result of Defendants' fraud, suppression and omission of material facts, the Plaintiff acted to his detriment in purchasing and using the Durom Cup, which they would not have purchased or used had they been told the truth.

129. As a result of Defendants' practices, Plaintiff has suffered actual damages in that he has purchased and used the Durom Cup which is dangerous and defective in that has caused and will continue to cause Plaintiff to suffer, expenses for medical testing, health monitoring and/or treatment.

130. As a result of the fraud by Defendants, Plaintiff has used a defective product, the Durom Cup, which has caused him to suffer.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT XII - BREACH OF IMPLIED WARRANTY

131. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

132. Defendants, as sellers of the Durom Cup, warranted that the product was safe for its intended purpose.

133. Plaintiff reasonably relied on the belief that the Durom Cup was reasonably safe and fit for its intended purpose.

134. Defendants breached this implied warranty because the Durom Cup released for public consumption had manufacturing and design defects and functioned improperly and was not safe and fit for its intended purpose.

135. Defendants' breach of this implied warranty was a proximate cause of Plaintiff's bodily injuries and damages.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT XIII - BREACH OF EXPRESS WARRANTY

136. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

137. Defendants expressly warranted that the Durom Cup would be reasonably safe and fit for its intended purpose.

138. Plaintiff reasonably relied on the express warranty of Defendants that the Durom Cup was reasonably safe and fit for its intended use.

139. The Durom Cup does not conform to the express warranties by Defendants because the product, as produced for public use, is defective and presents a high risk for injury to its intended users.

140. Defendants breached their express warranty regarding the safety and fitness of the Durom Cup.

141. Defendants' breach of their express warranty was a proximate cause of Plaintiff's bodily injuries and damages.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT XIV

STATUTORY CONSUMER FRAUD (815 ILCS 505/1 *et seq.*)

142. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

143. At all times relevant to this action, there was in effect the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 *et seq*. (the "Illinois Consumer Fraud Act" or "ICFA").

144. Section 2 of the Illinois Consumer Fraud Act, 815 ILCS 505/2, provides, in pertinent part, that:

> "Unfair methods of competition and unfair or deceptive acts or practices, including but not limited to the use or employment of any deception, fraud, false pretense, false promise, misrepresentation or the concealment, suppression or omission of any material fact, with intent that others rely upon the concealment, suppression or omission of such material fact, or the use or employment of any practice described in Section 2 of the "Uniform Deceptive Trade Practices Act", approved August 5, 1965, in the conduct of any trade or commerce are hereby declared unlawful whether any person has in fact been misled, deceived or damaged thereby. In construing this section consideration shall be given to the interpretations of the Federal Trade Commission and the federal courts relating to Section 5(a) of the Federal Trade Commission Act." 815 ILCS 505/2 (West 2002).

145. At all relevant times, the Plaintiffs and Defendants were "persons" within the meaning of 815 ILCS 505/1(c).

146. At all relevant times, the Plaintiffs were a "consumer" within the meaning of 815 ILCS 505/1(e).

147. At all relevant times, Defendants conducted "trade and commerce" within the meaning of 815 ILCS 505/1(f).

148. Defendants' offer for sale of a consumer product, the Durom Cup, in trade or commerce, constitutes a representation that the product, the Durom Cup, is reasonably safe for its intended purpose.

149. Defendants' offer for sale of the Durom Cup to Illinois consumers constitutes a representation that the Durom Cup is/was reasonably safe for its intended use.

150. Defendants have engaged in deceptive acts or practices, in violation of the Illinois Consumer Fraud and Deceptive Business Practices Act ("ICFA"), 815 ILCS 505/1-505/12, including, but not limited to, the following: (1) knowingly, intentionally, and/or recklessly omitting, concealing, and/or suppressing its own data from investigations and clinical trials, other analyses, studies, tests, understandings, and conclusions about the true efficacy of the Durom Cup; (2) knowingly, intentionally, and/or recklessly omitting, concealing, and/or suppressing its own data from investigations and clinical trials, other analyses, studies, tests, understandings, and conclusions about the safety of the Durom Cup; (3) knowingly, intentionally, and/or recklessly omitting, suppressing, and/or concealing the unreasonably dangerous nature of the Durom Cup; and (4) knowingly, intentionally, and/or recklessly omitting, concealing, and/or suppressing that use of the Durom Cup poses a significant increased risk of bodily harm and adverse events Defendants have violated the ICFA by, *inter alia*, consciously omitting, concealing, and/or suppressing, or otherwise failing to communicate and notify the Plaintiffs, purchasers and/or consumers of the Durom Cup, and the medical community at large, of the negative efficacy and/or safety information that it possessed.

151. The negative efficacy and/or safety information associated with the Durom Cup treatment, known by Defendants was a material fact in that the Plaintiffs would not have purchased the Durom Cup and would not have suffered injury from using the Durom Cup, if Defendants had not omitted, suppressed, and/or concealed, or otherwise failed to disclose the negative efficacy and safety information associated with the Durom Cup.

152. Defendants intended that the Plaintiffs rely upon these suppressions, concealment, and/or omissions as to the efficacy, description, quality, safety, and/or characteristics of the Durom Cup. Defendants' deceptive acts and/or practices were specifically designed and intended to induce the Plaintiffs to buy the Durom Cup and the deception occurred during a course of conduct involving trade or commerce.

153. As a direct and proximate result of the above violations of the ICFA, the Plaintiffs were actually deceived and such deception caused the Plaintiffs to suffer personal physical injury and actual damages. In addition to the increased risk of suffering bodily harm and adverse events, Plaintiffs expended value, *i.e.* money, for the purchase of an ineffective, unsafe, and/or unreasonably dangerous the Durom Cup.

154. Plaintiffs purchased the Durom Cup, manufactured, marketed, promoted, and sold by Defendants and suffered personal physical injury and an ascertainable loss of money, as a result of Defendants' use or employment of methods, acts or practices declared unlawful by the ICFA, and brings this action to recover money damages in the amount necessary to make him whole.

WHEREFORE, the Plaintiffs demand judgment in their favor and against Defendants in a sum in excess of the jurisdictional requirement of this Court; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

COUNT XV - UNJUST ENRICHMENT

155. Plaintiff repeats and realleges the allegations set forth in the paragraphs above as if fully set forth herein.

156. Defendants have been unjustly enriched in the amount of the profits they have earned as a result of Defendants' conduct as alleged herein.

157. Defendants have been unjustly enriched at the expense of and to the detriment of the Plaintiff.

WHEREFORE, the Plaintiff demands judgment in his favor and against Defendants in a sum in excess of $75,000.00; for costs herein incurred; attorneys fees; for such other and further relief as this Court deems just and proper.

DAMAGES

158. Plaintiff realleges and incorporates by reference each and every allegation contained in the foregoing paragraphs of this Complaint, and further alleges as follows:

159. As a direct and proximate result of the negligence, carelessness, recklessness, willful, intentional, deliberate and/or malicious acts of Defendants, individually and collectively, both jointly and severally, the Plaintiff suffered permanent bodily injury including, but not limited to, extensive hip, buttock, groin and leg pain following his implant, he still continues to suffer pain. The pain has limited his ability to perform basic day-to-day functions, all necessitating medical treatment and care.

WHEREFORE, the Plaintiff demands judgment of and from the Defendants, both jointly and severally, in such sums as will adequately compensate the Plaintiff and punish the Defendants for the bodily injuries and damages inflicted, as aforesaid, which said sums are far in excess of any sums necessary to confer the jurisdiction of this court, together with prejudgment and post-judgment interests, the costs expended in the prosecution of this lawsuit, including reasonable attorney fees, return or refund of all costs associated with the purchase of defective the Durom Cup, disgorgement of Defendants' profits from the sale of the Durom Cup, and do further pray for such other and further general relief as this court may deem proper.

THE PLAINTIFF FURTHER DEMANDS A TRIAL BY JURY.

Dated: 1-31-2011

Respectfully submitted,

BROWN AND CROUPPEN, P.C.

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